

EXPERT REPORT BY DAVID MAINE, M.D.

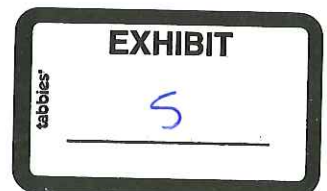
1. Background and Qualifications:

I am Board Certified in Anesthesiology with an additional specialty certificate in Pain Medicine. I have been licensed as a physician in Maryland since 2007. I obtained a Bachelor of Science in Neuroscience from the University of Rochester College of Arts and Sciences in 1998. I then obtained a Doctorate of Medicine from University of Rochester School of Medicine in Rochester, New York in 2002.

From 2002 to 2003, I completed an internship in Internal Medicine at The University of Maryland-Mercy Medical Center in Baltimore, Maryland. I then completed a residency in Anesthesiology at The Johns Hopkins University Hospital in Baltimore, Maryland from 2003 to 2006 and named Chief Resident of the Anesthesiology group in 2006. Following residency, I completed a Fellowship in Pain Medicine at The Johns Hopkins Hospital from 2006 to 2007. I have held board certifications from the American Board of Anesthesiology since 2007 and by the American Board of Anesthesiology Sub-Specialty – Pain Medicine since 2007.

From 2007 to present, I have served as the Medical Director of the Center for Interventional Pain Medicine at Mercy Medical Center in Baltimore, Maryland a multidisciplinary pain center emphasizing the treatment of acute and chronic pain conditions. In this role I serve as an anesthesiologist and pain management physician.

From July of 2007 to July 2009, I also served as a Clinical Associate at The Johns Hopkins Hospital in the Department of Anesthesiology and Critical Care Medicine in Baltimore, Maryland. I have served on the Pharmacy and Therapeutics Committee and the Institute for Cancer Care Committee at Mercy Medical Center since 2007. In 2010, I was appointed to the Medical Executive Committee at Mercy Medical Center and served on the Comprehensive Cancer Control



Plan Pain Management Committee with the Maryland Department of Health and Mental Hygiene from 2010 to 2013. I am currently the President of the medical staff at Mercy Medical Center and chair the medical executive committee.

I am a member of the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine. With respect to publications, I have authored and co-authored original articles, abstracts, book chapters, and newsletters in areas including, but not limited to, regional anesthesia, pain management, drug delivery methods, and epidural steroid injection.

A copy of my *curriculum vitae*, more fully setting forth my experience and professional accomplishments, is attached as Exhibit 1. Specific reference to the publications I have authored and/or co-authored in the previous 10 years are listed on my *curriculum vitae*.

2. List of Cases

I have testified as an expert at trial or by deposition in the past four (4) years. My case list is as follows:

- 1) *Bradley v. United* – 2013 (deposition)
- 2) *Asimenios v. State of MD* (administrative hearing) 2013
- 3) *Michelle Jackson v. insurance company* (deposition) 2014 (trial)
- 4) *C. Sheets v. insurance co* (deposition 2014)
- 5) *R. Moss v. insurer* - deposition 12/2013 (deposition)
- 6) *Dick v. Saaf* - Mont County 2015 (trial)
- 7) *M. Gallagher v. insurer* – 2015 (deposition)
- 8) *J. Holt v. insurer* – 2014 (deposition and trial)
- 9) *Wilder v. Univ of MD* – 2015 (deposition)
- 10) *H. Hurt v. Johnson Controls* -2015 (telephonic deposition)
- 11) *H. Garner v. insurer* -1/2015 (deposition)
- 12) *James Nugent v. Christopher S. O'Brien* – 10/2015 (deposition)
- 13) *M. Barkley v. insurer* 6/16 (deposition)
- 14) *L. Bunton v. insurer* 5/16 (deposition)
- 15) *Lula D. Mack Garrison v. MTA State of MD* – deposition 09-21-16

3. Facts and Data Considered in Forming My Opinions:

In forming my opinions, I have generally relied on my education, training, experience, and the materials I have reviewed. The following is a brief summary of the facts I rely upon in forming my opinions regarding Box Hill Surgery Center, LLC, Ritu Bhambhani, M.D., LLC, Ritu T. Bhambhani, M.D., LLC (collectively, “Box Hill Defendants” or “Box Hill”), and any agents or employees of the same.

a. Background for Dr. Bhambhani and Box Hill Surgery Center

Dr. Bhambhani is board certified in anesthesiology and pain medicine. In short, she graduated from medical school in 1994, and then did her post graduate training, including a residency and fellowship in anesthesiology and pain medicine, at the Cleveland Clinic in Ohio. She then obtained her Maryland license and began practicing anesthesiology and pain medicine in Maryland in 2000. She joined Harford County Ambulatory Surgery Center (in Maryland) in 2003, before opening Box Hill Surgery Center in 2008. Box Hill Surgery Center is a standalone ambulatory surgery center in Abingdon, Harford County, Maryland. Dr. Bhambhani is the sole owner and only regular physician at Box Hill, where she is also the Medical Director. Throughout the years, Dr. Bhambhani has practiced anesthesiology and pain medicine and has routinely performed different types of pain relieving procedures, including back and neck pain injections, including the ones at issue in this case. In my opinion, Dr. Bhambhani is experienced and well qualified to provide pain management services, among other things. Dr. Bhambhani is also qualified as an anesthesiologist and pain medicine expert to make decisions regarding the purchase of medications for a medical practice.

Box Hill Surgery Center has a nurse administrator, Andrew Vickers, RN. Mr. Vickers works part time with Dr. Bhambhani to assist her when performing pain injections and to assist

Exhibit 2

- FDA Form 483 to NECC
- FDA Form 483 to ARL
- Massachusetts BOP/DPH Preliminary Investigative Report
- Report from the Massachusetts Board of Pharmacy's May 2011 inspection of NECC
- NECC Indictment
- Congressional Memo: "FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?"
- NECC Environmental Monitoring Results
- NECC Cleaning Logs
- NECC Standard Operating Procedures
- Liberty clean room punch list (Ex. 1202)
- Logged Formula Worksheets for the Three Contaminated Lots of MPA
- Daily Fill Logs for the Recalled Lots of MPA
- ARL Testing Results for Three Recalled Lots of MPA
- Video from NECC's Surveillance Cameras
- Video from Inspections of NECC's Facility in December 2012 and July 2014
- Disks containing audio from Barry Cadden's Training for Sales Personnel
- Floorplan Showing the Layout of NECC's Facility
- Scientific Air Analysis Testing Results from 2011 and 2012
- Monthly Cleaning Logs Completed by UniClean Technicians
- Documents regarding a 2012 complaint to NECC from Massachusetts Ear and Eye Institute (the customer complaint)
- Joe Cabaleiro, RPH, New England Compounding Center Indictment, Int' J. Phar Compounding, March- April 2015, at 94.
- ASHP Guidelines (Ex. 1327)
- NECC Quality Assurance Report Cards for 2011 and 2012
- Notes from Keith St. John and Ian Wallis from conversations with NECC's Joe Connolly
- Drug Recall Charts
- NECC Customer List
- FDA Warning Letter to NECC-12/06 (Ex. 1309)
- NECC Letter (1/5/07) to FDA in Response to FDA 2006 Warning Letter (Ex. 1310)
- FDA Letter (10/31/08) to NECC in Response to NECC Response Letter (1/5/07) to FDA 2006 Warning Letter (Ex. 1311)
- FDA Email (7/17/12) Regarding Colorado Cease and Desist Order (5/10/11) and FDA Not Taking Further Action Against NECC at this time (Ex. 1312)
- Emails between NECC and UniClean (Deposition exhibits 422, 424, 426-431)
- Photographs of NECC's standing autoclave
- Photographs of the gaps in ceiling of cleanroom 1
- PCCA formula for compounding MPA
- NECC advertising materials provided to some customers
- New York Times article reporting on several Johnson & Johnson product recalls

- US Compounding, Inc. voluntary recall; 2014-2015 FDA inspections of US Compounding, Inc.; 2012 and 2015 US Compounding, Inc. website printouts
- USP 797
- USP 71
- USP 85
- Expert Report/Declaration of Dr. Philip Austin, Ph.D.
- Deposition of Philip Austin, Ph.D.
- Deposition/Report of Keith St. John
- Deposition/Report of Ian Wallis
- Deposition/Report of Ray Schneider
- Deposition/Report of Sheldon Bradshaw
- Deposition/Reports of Brian Reisetter
- Deposition of William Mixon
- Deposition/Report of Robert Guardino
- Deposition of Stephen O'Neill
- Deposition of Francis McAteer
- Deposition of Michael Cotugno
- Deposition of Edwin Cardona
- Deposition of Ricardo Dos Santos
- Deposition of Edgardo Camacho
- Deposition of Suneela Mistry
- Deposition of Jeffrey Erickson
- Deposition of George Pollick
- Deposition of Robert Kaiser
- Deposition of Michael Debeau
- Deposition of Thomas C. Kupiec
- Deposition of Tommy Means
- Deposition of Samuel Penta
- Depositions of YuZon Wu
- Deposition of Lucy Wilson, M.D.
- Deposition of Joseph Alessandrini, R.Ph.
- Deposition of Mario Giamei
- Deposition of Lisa Cadden
- Deposition of Steven Higgins
- Deposition of Owen Finnegan
- Deposition of Stephen Haynes
- Deposition of Cory Fletcher
- Deposition of Annette Robinson
- Deposition of Belmira Carvalho
- BHSC Responses to Request for Production of Documents (Bates 1-1586) including, among other things, AAAHC certifications and policies and procedures
- Deposition Transcript/Exhibits of Ritu Bhambhani, MD- Box Hill Surgery Center
- Deposition Transcript/Exhibits of Andrew Vickers, RN- Box Hill Surgery Center
- Deposition of Kimberly Brockmeyer

- Deposition of Barbara Wagner
- Expert Report of David Chason, MD
- Expert Report of Lloyd Saberski, MD
- Expert Report of Shmuel Shoham, MD
- Deposition of Lloyd Saberski – Circuit Ct Baltimore County, MD-Consolidated Cases
- Deposition/Report of Lawrence Winikur
- Deposition (Rule 31) of Faye Menter- Cumberland Valley Surgery Center
- Deposition (Rule 31) of Donald Bartnick- Annapolis Surgery Center
- Deposition (Rule 31) of Susan Calhoun-Peninsula Orthopaedics
- Deposition (Rule 31) of Charlotte Rhew-James Davis (Duke) Ambulatory Surgery Center
- Deposition (Rule 31) of Diana Holt-Premier Orthopedics & Sports Medicine-TN
- Deposition (Rule 31) of Laura Ross- Adams, DO-The Ross Center
- Deposition (Rule 31) of Kimberly Mason-University of Tennessee Medical Center
- Deposition (Rule 31) of James Cathey-East Tennessee Children's Hospital
- Deposition (Rule 31) of Noli Dominguez-Central Jersey Orthopedics
- Deposition (Rule 31) of Rhonda Proscia-The Montclair Orthopaedic Group- NJ

- **Angela Farthing, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-452

- **Linda Torbeck, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-148

- **Belinda Dreisch, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center (Bates nos.:1-187)

- **Teresa Davis, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-86

- **Edna Young, Patient, Deceased Evelyn Bowman, PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-82
- **John Millhausen, Patient, Deceased, Mary Joyce Armetta, PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-26
- **Bahman Kashi, Patient, Deceased, Kiumarc Kashi, PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-24
- **Brenda Rozek, Patient, Deceased, Meghan Handy, Individually and as Surviving Child & PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-39